

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA

v.

MAKSYM NIENADOV,
Defendant.

CRIMINAL NO. 4:19-CR-365

PLEA AGREEMENT

The United States of America, by and through Ryan K. Patrick, United States Attorney for the Southern District of Texas, Jeffrey Pearlman, Senior Trial Attorney, Sebastian A. Edwards, Assistant United States Attorney, and the defendant, MAKSYM NIENADOV (“Defendant”), and Defendant’s counsel, pursuant to Rule 11(c)(1)(A) of the Federal Rules of Criminal Procedure, state that they have entered into an agreement, the terms and conditions of which are as follows:

Defendant’s Agreement

1. Defendant agrees to plead guilty to Counts One, Two, Eight, and Eleven of the Superseding Indictment. Count One charges Defendant with Conspiracy, in violation of Title 18, United States Code, Section 371; Count Two charges Defendant with Introducing Misbranded Medicine in Interstate Commerce, in violation of Title 21, United States Code, Section 331(a); Count Eight charges Defendant with Trafficking in Counterfeit Drugs in violation of Title 18, United States Code, Section 2320(a); and Count Eleven charges Defendant with Smuggling Goods into the United States, in violation of Title 18, United States Code, Section 545. Defendant, by entering this plea, agrees that he is waiving any right to have the facts that the law makes essential to the punishment either charged in the superseding indictment, or proved to a jury or proven beyond a reasonable doubt.

Punishment Range

2. The statutory maximum penalty for each violation of Title 18, United States Code, Section 371, is imprisonment of not more than 5 years and a fine of not more than \$250,000. The statutory maximum penalty for each violation of Title 21, United States Code, Section 331(a), is imprisonment of not more than 3 years and a fine of not more than \$10,000. The statutory maximum penalty for each violation of Title 18, United States Code, Section 2320(a), is imprisonment of not more than 20 years and a fine of not more than \$5,000,000. The statutory maximum penalty for each violation of Title 18, United States Code, Section 545, is imprisonment of not more than 20 years and a fine of not more than \$250,000. Additionally, Defendant may receive a term of supervised release after imprisonment of up to three years. *See* Title 18, United States Code, Sections 3559(a)(3) and 3583(b)(2). Defendant acknowledges and understands that if he should violate the conditions of any period of supervised release which may be imposed as part of his sentence, then Defendant may be imprisoned for up to 2 years, without credit for time already served on the term of supervised release prior to such violation. *See* Title 18, United States Code, Sections 3559(a)(3) and 3583(e)(3). Defendant understands that he cannot have the imposition or execution of the sentence suspended, nor is he eligible for parole.

Mandatory Special Assessment

3. Pursuant to Title 18, United States Code, section 3013(a)(2)(A), immediately after sentencing, Defendant will owe to the Clerk of the United States District Court a special assessment in the amount of one hundred dollars (\$100.00) per count of conviction. The payment will be by cashier's check or money order, payable to the Clerk of the United States District Court, c/o District Clerk's Office, P.O. Box 61010, Houston, Texas 77208, Attention: Finance. If the

Defendant is indigent and unable to pay, the assessment may be waived by the Court or collected by the Bureau of Prisons.

Immigration Consequences

4. Defendant recognizes that pleading guilty will have consequences with respect to his immigration status. Defendant is not a citizen of the United States, and by pleading guilty he may be removed from the United States, denied citizenship, and denied admission to the United States in the future. Defendant's attorney has advised Defendant of the potential immigration consequences resulting from Defendant's plea of guilty, and Defendant affirms that he wants to plead guilty regardless of any immigration consequences that may result from the guilty plea and conviction.

Waiver of Appeal and Collateral Review

5. Defendant is aware that Title 28, United States Code, Section 1291, and Title 18, United States Code, Section 3742, afford a defendant the right to appeal the conviction and sentence imposed. Defendant is also aware that Title 28, United States Code, Section 2255, affords the right to contest or "collaterally attack" a conviction or sentence after the judgment of conviction and sentence has become final. Defendant knowingly and voluntarily waives the right to appeal or "collaterally attack" the conviction and sentence, except that Defendant does not waive the right to raise a claim of ineffective assistance of counsel on direct appeal, if otherwise permitted, or on collateral review in a motion under Title 28, United States Code, Section 2255. Defendant's knowing and voluntary waiver of the right to appeal or collaterally attack the conviction and sentence includes waiving the right to raise on appeal or on collateral review any argument that (1) the statute(s) to which the defendant is pleading guilty is unconstitutional and (2) the admitted

conduct does not fall within the scope of the statute(s). In the event Defendant files a notice of appeal following the imposition of the sentence or later collaterally attacks his conviction or sentence, the United States may assert its rights under this agreement and seek specific performance of these waivers, and at its sole discretion may reinstate charges that were dismissed or not prosecuted as a result of this Agreement.

6. In agreeing to these waivers, Defendant is aware that a sentence has not yet been determined by the Court. Defendant is also aware that any estimate of the possible sentencing range under the sentencing guidelines that he may have received from his counsel, the United States or the Probation Office, is a prediction and not a promise, did not induce his guilty plea, and is not binding on the United States, the Probation Office or the Court. The United States does not make any promise or representation concerning what sentence the defendant will receive other than concessions stated in this Agreement. Defendant further understands and agrees that the United States Sentencing Guidelines are “effectively advisory” to the Court. *See United States v. Booker*, 543 U.S. 220 (2005). Accordingly, Defendant understands that, although the Court must consult the Sentencing Guidelines and must take them into account when sentencing Defendant, the Court is not bound to follow the Sentencing Guidelines nor sentence Defendant within the calculated guideline range.

7. Defendant understands and agrees that each and all waivers contained in the Agreement are made in exchange for the concessions made by the United States in this plea agreement.

The United States' Agreements

8. The United States agrees to each of the following:

(a) If Defendant pleads guilty to Counts One, Two, Eight, and Eleven of the superseding indictment and persists in that plea through sentencing, and if the Court

accepts this plea agreement, the United States will move to dismiss any remaining counts of the indictment at the time of sentencing;

(b) If the Court determines that Defendant qualifies for an adjustment under section 3E1.1(a) of the United States Sentencing Guidelines, and the offense level prior to operation of section 3E1.1(a) is 16 or greater, the United States will move under section 3E1.1(b) for an additional one-level reduction because Defendant timely notified authorities of his intent to plead guilty, thereby permitting the United States to avoid preparing for trial and permitting the United States and the Court to allocate their resources more efficiently.

(c) The Government agrees to limit the calculated loss to the victim companies to a loss not to exceed \$700,000

Agreement Binding

9. The United States Attorney's Office for the Southern District of Texas agrees that it will not further criminally prosecute Defendant in the Southern District of Texas for offenses arising from conduct charged in the superseding indictment. This plea agreement binds only the United States Attorney's Office for the Southern District of Texas, the Computer Crime and Intellectual Property Section of the Department of Justice, and Defendant. It does not bind any other United States Attorney's Office. The United States Attorney's Office for the Southern District of Texas will bring this plea agreement and the full extent of Defendant's cooperation to the attention of other prosecuting offices, if requested.

United States' Non-Waiver of Appeal

10. The United States reserves the right to carry out its responsibilities under guidelines sentencing. Specifically, the United States reserves the right:

(a) to bring its version of the facts of this case, including its evidence file and any investigative files, to the attention of the Probation Office in connection with that office's preparation of a presentence report;

(b) to set forth or dispute sentencing factors or facts material to sentencing;

- (c) to seek resolution of such factors or facts in conference with Defendant's counsel and the Probation Office;
- (d) to file a pleading relating to these issues, in accordance with section 6A1.2 of the United States Sentencing Guidelines and Title 18, United States Code, section 3553(a); and
- (e) to appeal the sentence imposed or the manner in which it was determined.

Sentence Determination

11. Defendant is aware that the sentence will be imposed after consideration of the United States Sentencing Guidelines and Policy Statements, which are only advisory, as well as the provisions of Title 18, United States Code, Section 3553(a). Defendant nonetheless acknowledges and agrees that the Court has authority to impose any sentence up to and including the statutory maximum set for the offense(s) to which Defendant pleads guilty, and that the sentence to be imposed is within the sole discretion of the sentencing judge after the Court has consulted the applicable Sentencing Guidelines. Defendant understands and agrees that the parties' positions regarding the application of the Sentencing Guidelines do not bind the Court and that the sentence imposed is within the discretion of the sentencing judge. If the Court should impose any sentence up to the maximum established by statute, or should the Court order any or all of the sentences imposed to run consecutively, Defendant cannot, for that reason alone, withdraw a guilty plea, and will remain bound to fulfill all of the obligations under this plea agreement.

Rights at Trial

12. Defendant understands that by entering into this agreement, he surrenders certain rights as provided in this plea agreement. Defendant understands that the rights of a defendant include the following:

(a) If Defendant persisted in a plea of not guilty to the charges, defendant would have the right to a jury trial with the assistance of counsel. The trial may be conducted by a judge sitting without a jury if Defendant, the United States, and the court all agree.

(b) At a trial, the United States would be required to present witnesses and other evidence against Defendant. Defendant would have the opportunity to confront those witnesses and his attorney would be allowed to cross-examine them. In turn, Defendant could, but would not be required to, present witnesses and other evidence on his own behalf. If the witnesses for Defendant would not appear voluntarily, he could require their attendance through the subpoena power of the court; and

(c) At a trial, Defendant could rely on a privilege against self-incrimination and decline to testify, and no inference of guilt could be drawn from such refusal to testify. However, if Defendant desired to do so, he could testify on his own behalf.

Factual Basis for Guilty Plea

13. Defendant is pleading guilty because he is in fact guilty of the charges contained in Counts One, Two, Eight, and Eleven of the superseding indictment. If this case were to proceed to trial, the United States could prove each element of the offense beyond a reasonable doubt. The following facts, among others, establish Defendant's guilt:

Defendant MAKSYM NIENADOV, was involved with Healthy Nation, a group organized under the laws of Ukraine. Neither Defendant NIENADOV nor Co-Defendant Nikolaienko are medical practitioners or licensed by the law of any country to administer or dispense prescription drugs, however they both illegally sold prescription drugs.

Among the drugs illegally sold by NIENADOV and Nikolaienko were Epclusa, a prescription drug used to treat hepatitis; Abraxane, a prescription drug used to treat cancer; and Keytruda, a prescription drug used to treat cancer. Gilead Sciences, Inc. owns the trademark for the design identifying Epclusa and has the exclusive right to manufacture Epclusa for distribution in the United States; Celgene owns the trademark for the design identifying Abraxane and has the

exclusive right to manufacture Abraxane for distribution in the United States; and Merck & Co. owns the trademark for the design identifying Keytruda and has the exclusive right to manufacture Keytruda for distribution in the United States and Merck Sharp and Dohme (MSD) has the exclusive right to manufacture Keytruda for its worldwide distribution. At the time NIENADOV engaged in the sale and distribution of Epclusa, Abraxane, and Keytruda, he knew that he did not have trademark ownership or manufacturing rights for these drugs.

On June 15, 2018, NIENADOV, with the aid of Nikolaienko, began communicating via WhatsApp with an undercover U.S. Homeland Security Investigations (HSI) Agent in furtherance of the sale of Keytruda, Abraxane, and Epclusa in the United States. From June 15, 2018 to December 11, 2018, NIENADOV and Nikolaeinko conspired to illegally sell and distribute the following drugs quantities/prices to an undercover HSI Agent in United States:

- 1) Two boxes (50 mg) of Keytruda (\$2400);
- 2) Two boxes (50 mg) Keytruda and two boxes (5 mg/ml) Abraxane (\$3400); and
- 3) Two boxes (400mg/100mg – 28 tablets/box) Epclusa (\$6000).

At the direction of NIENADOV, the aforementioned drugs were shipped by Nikolaienko to an ICE undercover warehouse in Houston, Texas. The undercover HSI Agent wire transferred each payment to a (Ukrainian-based) Privatbank account identified in invoices provided by NIENADOV and Nikolaeinko.

Laboratory testing concluded that NIENADOV and Nikolaienko sold, in the United States, counterfeit Keytruda, Abraxane, and Epclusa drugs, and that these drugs violated the trademarks registered in the principal registry in the United States Patent and Trademark Office. The pharmaceuticals were counterfeit in that neither NIENADOV nor Nikolaienko had any authorization or license from the brand-holders to manufacture, make, sell, or traffic in any of the

legitimate pharmaceuticals. Furthermore, the counterfeit pharmaceuticals did not contain the active ingredients that were necessary for the drugs to serve their medical purpose and included fillers and adulterants that served no legitimate function for the conditions that they purported to cure and for which the owners manufactured the legitimate drugs to address. The pharmaceuticals were also counterfeit in that they were contained within counterfeit packages that bore labeling that the manufacturers had not authorized them to use and were falsely represented to be 1) Merck/MSD brand Keytruda, 2) Celgene brand Abraxane, and 3) Gilead brand Epclusa. Furthermore, the counterfeit packages often used false lot numbers, contained misspellings, and were printed in a manner inconsistent with the manufacturer's printing techniques. Lastly, if this case were called to trial, the United States would put on evidence from NIENADOV's email account showing orders for medical grade vials and containers which were later used to package counterfeit medicine.

On April 16, 2019, NIENADOV and Nikolaienko traveled to Houston, Texas in order to meet with undercover ICE Agents (UCs) whom they believed were future business partners/purchasers. During a meeting with the undercover ICE agents, NIENADOV and Nikolaienko discussed future unlawful shipments of pharmaceuticals to the United States. In order to facilitate such shipments, NIENADOV and Nikolaienko indicated that Healthy Nation could counterfeit the packaging of one of their products from Italian to U.S. government-approved packaging. They further agreed that if provided authentic Keytruda 100 packaging, Healthy Nation could have it copied, and repackage the Italian Keytruda in the U.S. counterfeit boxes. Later during the meeting, NIENADOV stated that he possessed Russian branded Keytruda that he could repackage this drug into authentic packaging provided by the undercover ICE agents.

NIENADOV assured the UCs that he would have the stickers to seal the boxes and that they could even duplicate the security holograms on the pharmaceutical packaging.

NIENADOV and Nikolaienko were arrested at the conclusion of their meeting with undercover ICE Agents. During the post-arrest search of their belongings, agents located counterfeit labeling for Iclusig, which is a cancer drug trademarked and manufactured by Takeda (pharmaceutical company).

Breach of Plea Agreement

14. If Defendant should fail in any way to fulfill completely all of the obligations under this plea agreement, the United States will be released from its obligations under the plea agreement, and Defendant's plea and sentence will stand. If at any time Defendant retains, conceals, or disposes of assets in violation of this plea agreement, or if Defendant knowingly withholds evidence or is otherwise not completely truthful with the United States, then the United States may move the Court to set aside the guilty plea and reinstate prosecution. Any information and documents that have been disclosed by Defendant, whether prior to or subsequent to this plea agreement, and all leads derived therefrom, may be used against defendant in any prosecution if the Defendant commits a breach of this Plea Agreement.

Restitution, Forfeiture, and Fines – Generally

15. This Plea Agreement is being entered into by the United States on the basis of Defendant's express representation that he will make a full and complete disclosure of all assets over which he exercises direct or indirect control, or in which he has any financial interest. Defendant agrees not to dispose of any assets or take any action that would effect a transfer of property in which he has an interest, unless Defendant obtains the prior written permission of the United States.

16. Defendant agrees to make complete financial disclosure by truthfully executing a sworn financial statement (Form OBD-500 or similar form) within 14 days of signing this plea agreement. Defendant agrees to authorize the release of all financial information requested by the United States, including, but not limited to, executing authorization forms permitting the United States to obtain tax information, bank account records, credit histories, and any other information, that the Government requests. Defendant agrees to discuss and answer any questions by the United States relating to Defendant's complete financial disclosure.

17. Defendant agrees to take all steps necessary to pass clear title to forfeitable assets to the United States and to assist fully in the collection of restitution and fines, including, but not limited to, surrendering title, executing a warranty deed, signing a consent decree, stipulating to facts regarding the transfer of title and the basis for the forfeiture, and signing any other documents necessary to effectuate such transfer. Defendant also agrees to direct any banks which have custody of his assets to deliver all funds and records of such assets to the United States, by executing any releases, waivers, or other documents provided by the Government

18. Defendant understands that forfeiture, restitution, and fines are separate components of sentencing and are separate obligations.

Restitution

19. Defendant agrees to entry of an Order requiring payment of full restitution to the victim(s) if any, regardless of the count(s) of conviction. Defendant understands and agrees that the Court will determine the amount of restitution to fully compensate the victim(s). Defendant agrees that restitution imposed by the Court will be due and payable immediately and that Defendant will not attempt to avoid or delay payment. Subject to the provisions of paragraph 5

above, Defendant waives the right to challenge in any manner, including by direct appeal or in a collateral proceeding, the restitution order imposed by the Court.

Forfeiture

20. Defendant stipulates and agrees that the property listed in the Superseding Indictment's Notice of Forfeiture (and in any supplemental Notices) is subject to forfeiture, and Defendant agrees to the forfeiture of that property. Defendant stipulates and admits that one or more of the conditions set forth in Title 21, United States Code, section 853(p), exists.

21. Defendant agrees to waive any and all interest in any asset which is the subject of a related administrative or judicial forfeiture proceeding, whether criminal or civil, federal or state.

22. Defendant consents to the order of forfeiture becoming final as to Defendant immediately following this guilty plea, pursuant to Federal Rule of Criminal Procedure 32.2(b)(4)(A).

23. Subject to the provisions of paragraph 5 above, Defendant waives the right to challenge the forfeiture of property in any manner, including by direct appeal or in a collateral proceeding.

Fines

24. Defendant understands that under the Sentencing Guidelines the Court is permitted to order Defendant to pay a fine that is sufficient to reimburse the government for the costs of any imprisonment or term of supervised release, if any. Defendant agrees that any fine imposed by the Court will be due and payable immediately, and Defendant will not attempt to avoid or delay payment. Subject to the provisions of paragraph 5 above, Defendant waives the right to challenge the fine in any manner, including by direct appeal or in a collateral proceeding.

Complete Agreement

25. This written plea agreement, consisting of 16 pages, including the attached addendum of Defendant and his attorney, constitutes the complete plea agreement between the United States, Defendant, and Defendant's counsel. No promises or representations have been made by the United States except as set forth in writing in this plea agreement. Defendant acknowledges that no threats have been made against him and that he is pleading guilty freely and voluntarily because he is guilty.

26. Any modification of this plea agreement must be in writing and signed by all parties.

Filed at Houston, Texas, on July 17, 2020.

/s/ Maksym Nienadov*

Defendant

*Electronically signed for Mr. Nienadov with his permission and after consultation pursuant to Southern District of Texas General Order 2020-11.

Subscribed and sworn to before me on July 17, 2020.

DAVID J. BRADLEY, Clerk
UNITED STATES DISTRICT CLERK

By: Cynthia Jantowski
Deputy United States District Clerk

APPROVED:

Ryan K. Patrick
United States Attorney

By: Sebastian A. Edwards
Jeffrey Pearlman
Senior Trial Attorney


John MacVane
Attorney for Defendant

U.S. Department of Justice (CCIPS)

Sebastian A. Edwards
Assistant United States Attorney
Southern District of Texas

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CRIMINAL NO. 4:19-CR-365

PLEA AGREEMENT -- ADDENDUM

I have fully explained to Defendant his rights with respect to the pending indictment. I have used the services of a translator, fluent in the Russian language, which the Defendant understands. I have reviewed the provisions of the United States Sentencing Commission's Guidelines Manual and Policy Statements and I have fully and carefully explained to Defendant the provisions of those Guidelines which may apply in this case. I have also explained to Defendant that the Sentencing Guidelines are only advisory and the court may sentence Defendant up to the maximum allowed by statute per count of conviction. Further, I have carefully reviewed every part of this plea agreement with Defendant. To my knowledge, Defendant's decision to enter into this agreement is an informed and voluntary one.


John MacVane
Attorney for Defendant

7/17/2020

Date

I have consulted with my attorney and fully understand all my rights with respect to the indictment pending against me. My attorney has fully explained, and I understand, all my rights with respect to the provisions of the United States Sentencing Commission's Guidelines Manual which may apply in my case, and that the Court will consult the Sentencing Guidelines but is not required to impose my sentence advised by the Guidelines I have read and carefully reviewed every part of this plea agreement with my attorney. I understand this agreement and I voluntarily

agree to its terms.

/s/ Maksym Nienadov*

Defendant

7/17/2020

Date

*Electronically signed for Mr. Nienadov with his permission and after consultation pursuant to Southern District of Texas General Order 2020-11.